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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/583,658

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Rachid Zegdi

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EXAMINER

MILLER, CHERYL L

ART UNIT

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/583,658	<b>Applicant(s)</b> ZEGDI, RACHID	
	<b>Examiner</b> CHERYL MILLER	<b>Art Unit</b> 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 August 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Response to Arguments***

Applicant's arguments filed August 19, 2008 have been fully considered but they are not persuasive.

The applicant has argued that Garrison (US 6,425,916 B1) does not disclose a resilient carrier frame biased to the deployed configuration. The examiner disagrees. Garrison's carrier frame (26, 26a) is disclosed to be either balloon expandable *or* self-expanding. When self-expanding (col.8, lines 13-21; col.9, lines 1-10; see figs.16-22), it is biased to the deployed configuration. The applicant has also argued that protrusions (34), barbs (100), and commissural posts (32) may not be considered centripetal compression means. The examiner disagrees. Any of 34, 100, or 32 may function as a means to compress, as these structures are resilient and may be grasped by an instrument to compress the frame to the folded configuration. The applicant has further argued that Garrison's shutter (valve leaflets) are not contracted transversely to allow flow therethrough. The examiner disagrees. First it is noted that this statement is relatively indefinite, as a transverse plane has not been claimed (as to its relative positioning). Also, it is unclear as to what applicant is referring to at the recitation "contracted transversely". Garrison's leaflets lie transversely across the lumen in a closed or "obstructed" position and lay parallel to the lumen when in the open or "released" position. The leaflets may be considered to be contracted transversely as the membranes have been contracted or compressed at the periphery on the transverse plane. If applicant were to claim that in the open or "released" position, portions of the shutter are contracted transversely toward the central axis, or somehow claim the

Art Unit: 3738

positioning of the shutter edges near the central axis, such language would seemingly overcome the Garrison rejection

The applicant has argued that Fogarty (US 6,939,365 B1) does not disclose carrier frame to be resilient and elastically deformable. The examiner disagrees. Fogarty discloses use a valve with carrier frame (valve 68) for example one disclosed by Lane (US 6,371,983) incorporated by reference. Lane's frame has resilient elastic struts that attach to leaflets (shutter). The applicant has also argued that Fogarty's scallop gaps (322) may not be considered the centripetal compression means. The examiner disagrees. The gap (322) provides the means to be compressed and removed (see col.14, lines 25-40). Further, the clamp or scissors may also be considered the compression means. The applicant has also argued that Fogarty's leaflets are not contracted transversely in the released (open) position. The examiner disagrees. The leaflets may be considered to be contracted transversely as the membranes have been contracted or compressed at the periphery on the transverse plane. If applicant were to claim that in the open or "released" position, portions of the shutter are contracted transversely toward the central axis, or somehow claim the positioning of the shutter edges near the central axis, such language would seemingly overcome the Fogarty rejection

The applicant has argued that Vesely (US 6,530,952 B2) does not disclose a resilient elastic carrier frame. The examiner disagrees. Vesely's frame is elastically deformable about the hinges of articulation and biased in the deployed configuration (see col.9, lines 33-44). It is collapsible (fig.3c) and expandable (fig.3a), where it is locked into position. The applicant has also argued that Vesely's leaflets are not contracted transversely in the released (open) position. The examiner disagrees. The leaflets may be considered to be contracted transversely as the

Art Unit: 3738

membranes have been contracted or compressed at the periphery on the transverse plane. If applicant were to claim that in the open or “released” position, portions of the shutter are contracted transversely toward the central axis, or somehow claim the positioning of the shutter edges near the central axis, such language would seemingly overcome the Vesely rejection.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "it" in lines 14 and 15. There is insufficient antecedent basis for this limitation in the claim. It appears applicant intended to refer to the shutter, however it is unclear.

Claim 1 also recites, "is extended transversely", however it is unclear what direction is transversely. That is, transverse to what? This limitation is considered indefinite. Applicant may want to consider defining the tubular endoprosthesis to have a lumen and then the shutter to extend transverse to the lumen. Claims 2-16 depend upon claim 1 and inherit all problems with the claim.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 3738

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-9, 11, 12, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Garrison et al. (US 6,425,916 B1). Garrison discloses a kit (fig.9) comprising a tubular endoprosthesis (8) and a prosthetic valve (6), the valve for removably implanting in the endoprosthesis (is unattached separate component, thus has capability of being removed therefrom), the valve(6) having a resilient deformable carrier frame (26; col.8, lines 14-21; col.9, lines 1-10), flexible shutter (leaflets 38), and centripetal compression means (100 or 34 act as means as they are capable of being grasped by a tool; further, windings of frame 28, 30 or 32 may act as means also) for compressing the carrier frame. Garrison discloses the shutter (leaflets 38) to have an obstructed position (closed) in which it is extended transverse to the lumen (see fig.11) and a released position when the shutter is contracted transversely (leaflets open to be parallel with lumen thus are contracted along the transverse plane, at the rim/perimeter of the valve). Garrison discloses the shutter (38) to be a pouch having an orifice (seen in fig.11), the kit being hemispherical at a wall (leaflets 39 form cupped surface when closed; fig.29, 30). Garrison discloses the compression means to comprise a clamp having branches (each branch being considered a strut of 28 or 30) connected at a common region (bend in frame), the branches connected to the shutter (see fig.9, 10, 29, 30) in a connection segment and the branches (struts) having a drive segment (for example 32) capable of co-operating with a clamp member (has such capability of being grasped by a tool). Garrison discloses the branches (struts

Art Unit: 3738

of frame) to be welded together, fork shaped, and deformable (fig.9, 10, 29, 30). Garrison discloses the valve (6) to have threads (sutures (col.5, lines 44-48) connecting the pouch (38) to the branches (struts of frame). Garrison discloses the valve (6) disposed inside the tubular endoprosthesis (8). Garrison discloses implanting the endoprosthesis (8) and valve (6) endoluminally (fig.17-19, 23-26). The valve is considered *removable* (capable of being removed).

Claims 1-3, 11-13, and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Vesely (US 6,530,952 B2). Vesely discloses a kit comprising a tubular endoprosthesis (10 or 100; fig.2, 10) and a prosthetic valve, the valve for removably implanting in the endoprosthesis, the valve having a resilient deformable carrier frame (21 or 110; col.9, lines 33-44), flexible shutter (120), and centripetal compression means (144 or 180) for compressing the carrier frame (col.13, lines 60-62). Vesely discloses the shutter (120) to be a pouch and having an orifice (seen in fig.27a). Vesely discloses the valve disposed inside the tubular endoprosthesis (fig.27a). Vesely discloses implanting the endoprosthesis (10 or 100) and valve (21 or 110) endoluminally (through a lumen) and removing the valve and replacing it with a new one (col.3, lines 11-12; col.5, lines 5-10; col.9, lines 1-5). Vesely's shutter (leaflets) transverse the lumen when closed and are contracted at the rim of the valve along the transverse plane when open.

Claims 1, 2, 4, 11-13, and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Fogarty et al. (US 6,939,365 B1). Fogarty discloses a kit comprising a tubular endoprosthesis (2) and a prosthetic valve (68), the valve for removably implanting in the endoprosthesis (inserted in fig.69, 70, removed in fig.82-84), the valve (68) having a deformable carrier frame (frame shown deformed in fig.84; see Lane incorporated by reference patent US 6,371,983 for

Art Unit: 3738

details of valve), flexible shutter (leaflets seen in fig.69, 70; col.13, lines 1-4), and centripetal compression means (gap322) for compressing the carrier frame (figs.82-84). Fogarty discloses the shutter to be a pouch (see fig.69, 70). Fogarty discloses the valve (68) disposed inside the tubular endoprosthesis (2). Fogarty discloses implanting the endoprosthesis and valve endoluminally (through the lumen, fig.53, 69) and removing the valve (fig.84) and replacing it with a new one (col.14, lines 25-41).

Claims 1, 2, 4-9, 11, 12, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Johnson (US 4,339,831, cited in IDS). Johnson discloses a kit comprising a tubular endoprosthesis (50; seen in fig.6) and a prosthetic valve (seen in fig.2), the valve configured to be implanted in and withdrawn from the endoprosthesis (the two are separate components, prior to suturing to the vessel wall, the valve is configured to be implanted in or withdrawn from the endoprosthesis 50), the valve comprising a resilient carrier frame (10+12+14; seen in fig.1) that is elastically deformable and biased to a deployed position (seen in fig.2; col.4, lines 22-25), and a flexible shutter (30) connected to the frame (see fig.2) the shutter deformable between an obstructed position which it is extended transversely (see fig.2, 3) and a released position which it is contracted transversely (see fig.5), and an integrated centripetal compression means (joint 16 of frame) for compressing the frame into the folded configuration (joint 16 forms a clamp which may be grasped by an instrument to compress the frame; it acts as a means to allow compression by its shape and resiliency). Johnson discloses the shutter (30) to comprise a hemispherical pouch with an end wall (seen in fig.2). Johnson discloses the compression means (frame near 16) to comprise at least two branches (10, 12, 14) connected at a common region (16) each branch having a connection segment connected to the shutter (near free ends or at 18, 20, 22) and



Art Unit: 3738

a drive segment (portions of 10, 12, 14 near other end 16). Johnson discloses a plurality of threads (sutures, sewn; col.5, lines 8-12) connecting the branches to the pouch. Johnson discloses implanting the tubular prosthesis in a duct endoluminally and then implanting the valve inside the endoprosthesis (col.5 line 61-col.6 line7) it is considered removably implanted, as it may be surgically removed at any time).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10, 14, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vesely (US 6,530,952 B2). Vesely discloses a kit substantially as claimed. Vesely discloses a carrier frame (21 or 110) having a constriction strand (32; fig.24, 26, 30) engaged around the frame. Vesely has shown a frame (21, 110) and disclosed the possibility of alternate valve frame to be used with the invention (col.8, lines 24-30), however is silent to mention specifics (such as the claimed mesh frame). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Vesely's kit with valve frame and disclosure of alternate frame structures, with a known mesh frame, since such a frame is known in the art and would be considered an "alternate" frame structure used by Vesely.

### ***Conclusion***

Art Unit: 3738

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHERYL MILLER whose telephone number is (571)272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4755. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cheryl Miller/  
Examiner, Art Unit 3738

/Corrine M McDermott/  
Supervisory Patent Examiner, Art Unit 3738

Application/Control Number: 10/583,658

Page 10

Art Unit: 3738